REMARKS

As an initial issue, Applicant wishes to thank the Examiner Tran for her interview on March 28, 2006.

Claims 1-154 stand rejected in the Office Action dated December 7, 2005. Applicants have deleted claims 1-154 by this amendment, but reserve the right to pursue these claims in a continuation application. New claims 155-172 have been added. Upon entry of the amendments, claims 155-172 remain pending.

The new claims correspond to those which were presented and discussed at the recent interview. These claims are believed to place the application in condition for allowance. All of the new claims are directed to a modified-release tablet suitable for use in a once daily administration of bupropion treatment regiment, wherein the modified-release tablet is bioequivalent to Wellbutrin or Zyban/Wellbutrin SR tablets over a 24-hour period or the use thereof as a once-a-day medicament

Support for the new claims is found throughout the specification. However, in an attempt to advance prosecution and to assist the Office in evaluating the proposed new claims, Applicants have identified the following particular passages and sections of the application as filed that provide support for the new claims:

Claims	Support
155	For example: Tables 21, 22, 23, 24 and paragraphs [0035], [0156] and [0164]. Definition of "bioequivalence" can be found for example in paragraphs [0140] and [0148].
156	Paragraph [0035] and Tables 18 and 20
157	Paragraph [0084]
158	Paragraphs [0034] and [0095]
159	Paragraph [0035] and Tables 18 and 20
160	Paragraph [0067]
161	Paragraph [0067]

162	Paragraph [0067]
163	Paragraph [0091]
164	Paragraph [0091]
165	Tables 15a, 17 and 19
166	Tables 15a and 19
167	Table 15a
168	Paragraph [0065] and paragraphs [0014] and [0094] for functionality of moisture barrier as an inhibitor of degradation of bupropion.
169	Use of bupropion for treatment of depression is well known in the prior art.
170 and 171	See support for claims 166 and 167
172	Paragraph [0018]

Applicant is presenting the foregoing amendments for the sole purpose of advancing the prosecution of the application. As shown by the foregoing demonstrated support in the as-filed specification, no new matter is presented by any of these amendments or new claims. Accordingly, the application is believed to be in condition for allowance and such favorable action is earnestly solicited.

Claim Rejections -35 USC §112

Previous claim 138 was rejected under 35 USC §112 as being indefinite in the use of the phrase "salt of bupropion hydrochloride". Claim 138 has been deleted in this response and accordingly this rejection is now rendered moot.

Claim Rejections – 35 USC §102

Claims 1-3, 6, 7, 14-44, 54-65, 67, 68, 72, 75-78, 91-115 and 123-128 stand rejected as being anticipated by US Patent No. 6,143,327 to Seth. These claims have now been deleted and accordingly this rejection is now rendered moot.

Applicants respectfully submit that the new claims patentably distinguish over the prior art of record as the Seth '327 Patent neither teaches nor suggests a once a day modified release tablet of buproprion that is bioequivalent to the marketed Wellbutrin (immediate release form of buproprion) or Zyban/Wellbutrin SR (sustained release form of bupropion). [As explained in the as-filed patent application, "bioequivalency" and "bioequivalent" are defined in the subject application according to accepted FDA guidelines conventional in the industry.] Prior to the present invention such a bioequivalent bupropion formulation had not been reported or made publicly available. Rather, the previous extended release bupropion formulations, i.e., Wellbutrin and Zyban/Wellbutrin SR require administration more than once a day.

In this regard, the comparative Example 8 on page 53, paragraph [0165] of the application as-filed unequivocally shows that a formulation made according to the Seth '327 Patent is not bioequivalent to Wellbutrin or Zyban/Wellbutrin SR. The data therein shows that the pharmacokinetic and bioavailability data of the Seth formulation relative to the reference product, Wellbutrin or Zyban/Wellbutrin SR tablets, does not fall within the FDA 80%-125% range for a product to be bioequivalent and therefore the product made according to Seth is not bioequivalent to Wellbutrin or Zyban/Wellbutrin SR. Accordingly, Applicants respectfully submit that the present claims are not anticipated by the prior art of record.

Claim Rejections – 35 USC §103

Claims 1-3, 6-48, 54-69, 72, 75-115 and 123-140 stand rejected under 35 USC §103(a) as being unpatentable over US Patent No. 6,143,327 to Seth. Further, claims 1-140 stand rejected as being unpatentable under 35 USC §103(a) over Seth in view of US Published Patent Application No. 2004/0228915 to Noack et al. Additionally, Claims 141-154 stand rejected over Seth in view of US Patent No. 5,763,493 to Ruff et al. Given that these claims have all been deleted by this response, the Office's rejection of these claims is now respectfully rendered moot. However, for completeness these rejections are addressed below.

Applicants respectfully submit that the present claims are not obvious over Seth. Nothing in Seth provides the requisite motivation to the skilled artisan to modify the teachings therein to arrive at a once a day formulation that possesses the recited bioequivalency properties, i.e., is bioequivalent to Wellbutrin or Zyban/Wellbutrin SR. The Office has stated that: "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not". It is anticipated that this basis of the rejection is no longer applicable based on the newly recited claims. Indeed, Applicants respectfully submit that this burden has been clearly met by showing that a product made according to the teachings of Seth is not bioequivalent to Wellbutrin or Zyban/Wellbutrin SR (see paragraph [0010] and Comparative Example 8 in the specification as filed). Accordingly, Applicants respectfully submit the claims are patentably distinct over Seth under 35 USC §103(a).

Applicants also submit that neither Noack nor Ruff provide any teaching, suggestion or motivation to the skilled artisan to modify the teachings therein to arrive at a once a day bupropion formulation that is bioequivalent to Wellbutrin or Zyban/Wellbutrin SR. Applicants further submit that there is nothing in Seth and Noack or Seth and Ruff that would motivate the skilled artisan to combine the teachings to arrive at the presently claimed invention. This is especially true given the showing that Seth itself cannot lead to a once a day formulation that is also bioequivalent to Wellbutrin or Zyban/Wellbutrin. Accordingly, Applicants respectfully submit that the present claims are patentably distinct over Seth in view of Noack and Seth in view of Ruff.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

If the Office has any questions regarding this Response or the application in general it is respectfully requested to contact the undersigned so that prosecution may be expedited.

The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-0206 (Docket # 54030US).

Respectfully submitted,

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